CHAPTER 1.4.5.

INTERNATIONAL TRANSFER AND LABORATORY CONTAINMENT OF ANIMAL PATHOGENS

Article 1.4.5.1.

Object

To prevent the introduction and spread of animal diseases caused by pathogens.

Article 1.4.5.2.

Introduction

1. The consequences of the introduction into a country of an infectious disease or an animal pathogen or new strain of animal pathogen from which it is currently free, are potentially very serious. This is because animal health, human health, the agricultural economy and trade may all be adversely affected to a greater or a lesser degree. Countries will already have in place a range of measures, such as requirements for pre-import testing and quarantine, to prevent such introductions through the importation of live animals or their products.

2. However, there is also the risk that disease may occur as a result of the accidental release of animal pathogens from laboratories that are using them for various purposes such as research, diagnosis or the manufacture of vaccines. Such pathogens may already occur in the country or they may have been imported deliberately or inadvertently. It is therefore necessary to have in place measures to prevent their accidental release. These measures may be applied either at national borders by prohibiting or controlling the importation of specified pathogens or their carriers ~~(see Article 1.4.5.7.)~~ or within national boundaries by specifying the conditions under which laboratories must handle them. In practice, a combination of external and internal controls is likely to be applied depending on the risk to animal health posed by the pathogen in question.

Article 1.4.5.3.

Classification of pathogens

Pathogens should be categorised according to the risk they pose to both human and animal health. They are grouped into four risk categories. Detailed information is provided in the *Terrestrial Manual.*

~~Article 1.4.5.3.~~

~~**Purpose**~~

~~1) To provide guidance on the laboratory containment of animal pathogens according to the risk they pose to animal health and the agricultural economy of a country, particularly when the disease they cause is not enzootic.~~

~~2) To provide guidance on the import conditions applicable to animal pathogens.~~

~~3) Where animal pathogens also pose a risk to human health, guidance on their laboratory containment should be sought from the *Terrestrial Manual* and other relevant published documents.]~~

Article 1.4.5.4.

Importation of animal pathogens

1. The importation of any animal pathogen, *pathological material* or organisms carrying the pathogen should be permitted only under an import licence issued by the relevant authority. The import licence should contain conditions appropriate to the risk posed by the pathogen and, in relation to air transport, the appropriate standards of the International Air Transport Association concerning the packaging and transport of hazardous substances. The import licence for risk groups 2, 3 or 4 should only be granted to a laboratory that is licensed to handle the particular pathogen as in Article 1.4.5.5.

2. When considering applications to import *pathological material* from other countries, the authorities should have regard to the nature of the material, the animal from which it is derived, the susceptibility of that animal to various diseases and the animal health situation of the country of origin. It may be advisable to require that material is pre-treated before import to minimise the risk of inadvertent introduction of a pathogen.

~~Article 1.4.5.4.~~

~~**Classification of animal pathogens**~~

~~1) Animal pathogens should be categorised on the risk they pose to animal health, should they be introduced into a country or accidentally released from a laboratory. In categorising pathogens into four groups according to containment requirements, the following factors should be taken into account: the organism's pathogenicity, the biohazard it presents, its ability to spread, the economic aspects and the availability of prophylactic and therapeutic treatments.~~

2) Some pathogens need to be transmitted by specific vectors or require intermediate hosts to complete their life cycles before they can infect animals and cause disease. In countries where such vectors or intermediate hosts do not occur, or where climatic or environmental factors mitigate against their survival, the pathogen poses a lower risk to animal health than in countries where such vectors or intermediate hosts occur naturally or could survive.

3) When categorising animal pathogens into specific groups, the following criteria should be taken into account:

a) Group 1 animal pathogens

Disease producing organisms which are enzootic but not subject to official control.

b) Group 2 animal pathogens

Disease producing organisms which are either exotic or enzootic but subject to official control and which have a low risk of spread from the laboratory.

i) They do not depend on vectors or intermediate hosts for transmission.

ii) There is a very limited or no transmission between different animal species.

iii) Geographical spread if released from the laboratory is limited.

iv) Direct animal to animal transmission is relatively limited.

v) The need to confine diseased or infected non-diseased animals is minimal.

vi) The disease is of limited economic and/or clinical significance.

c) Group 3 animal pathogens

i) Disease producing organisms which are either exotic or enzootic but subject to official control and which have a moderate risk of spread from the laboratory.

ii) They may depend on vectors or intermediate hosts for transmission.

iii) Transmission between different animal species may readily occur.

iv) Geographical spread if released from the laboratory is moderate.

v) Direct animal to animal transmission occurs relatively easily.

vi) The statutory confinement of diseased, infected and in-contact animals is necessary.

vii) The disease is of severe economic and/or clinical significance.

viii) Prophylactic and/or therapeutic treatments are not readily available or of limited benefit.

d) Group 4 animal pathogens

Disease producing organisms which are either exotic or enzootic but subject to official control and which have a high risk of spread from the laboratory.

i) They may depend on vectors or intermediate hosts for transmission.

ii) Transmission between different animal species may occur very readily.

iii) Geographical spread if released from the laboratory is widespread.

iv) Direct animal to animal transmission occurs very easily.

v) The statutory confinement of diseased, infected and in-contact animals is necessary.

vi) The statutory control of animal movements over a wide area is necessary.

vii) The disease is of extremely severe economic and/or clinical significance.

viii) No satisfactory prophylactic and/or therapeutic treatments are available.

Article 1.4.5.5.

Containment levels

1) The principal purpose of containment is to prevent the escape of the pathogen from the laboratory into the national animal population. Some animal pathogens can infect man. In these instances the risk to human health may demand additional containment than would otherwise be considered necessary from purely animal health considerations.

2) The level of physical containment and biosecurity procedures and practices should be related to the group into which the pathogen has been placed, and the detailed requirements should be appropriate to the type of organism (i.e. bacterium, virus, fungus or parasite). The lowest containment level will be required for pathogens in group 1 and the highest level for those in group 4. Guidance on the containment requirements for groups 2, 3 and 4 is provided in Table 1.

3) Arthropods may be pathogens or vectors for pathogens. If they are a vector for a pathogen being used in the laboratory, the appropriate containment level for the pathogen will be necessary in addition to the containment facilities for the arthropod.

~~Article 1.4.5.6.~~

~~**Possession and handling of animal pathogens**~~**]**

Article 1.4.5.5.

Laboratory containment of animal pathogens

1. Guidance on the laboratory containment of animal pathogens and on the import conditions applicable to animal pathogens is found in the Chapter I.1.6. of the *Terrestrial Manual*. Additional guidance on human safety is also found in this chapter.

2. A laboratory should be allowed to possess and handle animal pathogens in group 3 or 4 only if it can satisfy the relevant authority that it can provide containment facilities appropriate to the group. However, depending on the particular circumstances of an individual country, the authority might decide that the possession and handling of certain pathogens in group 2 should also be controlled. The authority should first inspect the facilities to ensure they are adequate and then issue a licence specifying all relevant conditions. There should also be a requirement for appropriate records to be kept and for the authority to be notified if it is suspected that a material being handled contains a pathogen not covered by the licence. The authority should visit the laboratory periodically to ensure compliance with the licence conditions. It is important that authority staff carrying out the visit should not have any contact with species susceptible to the pathogens being handled at the laboratory for a specified period after visiting the laboratory. The length of this period will depend on the pathogen.

3. Licences should specify:

    a) how the pathogen is to be transported and the disposal of the packaging;

    b) the name of the person responsible for the work;

    c) whether the pathogen may be used *in vivo* (and if so whether in laboratory animals or other animals) and/or only *in vitro*;

    d) how the pathogen and any experimental animals should be disposed of when the work is completed;

    e) limitations on contact by laboratory staff with species susceptible to the pathogens being used;

    f) conditions for the transfer of pathogens to other laboratories;

    g) specific conditions relating to the appropriate containment level and biosecurity procedures and practices.

Table 1. Guidance on the laboratory requirements for the different containment groups

-	CONTAINMENT GROUP		
REQUIREMENTS OF THE LABORATORY	**2**	**3**	**4**
A)Laboratory siting and structure	-	-	-
1.Not next to known fire hazard	Yes	Yes	Yes
2.Workplace separated from other activities	Yes	Yes	Yes
3.Personnel access limited	Yes	Yes	Yes
4.Protected against entry/exit of rodents and insects	Yes	Yes	Yes
5.Liquid effluent must be sterilised	-	Yes and monitored	Yes and monitored
6.Isolated by airlock. Continuous internal airflow	-	Yes	Yes
7.Input and extract air to be filtered using HEPA or equivalent	-	Single on extract	Single for input, double for extract
8.Mechanical air supply system with fail-safe system	-	Yes	Yes
9.Laboratory sealable to permit fumigation	-	Yes	Yes
10.Incinerator for disposal of carcasses and waste	Available	Yes	Yes on site
B)Laboratory facilities			
11.Class 1/2/3 exhaust protective cabinet available	Yes	Yes	Yes
12.Direct access to autoclave	Yes	Yes with double doors	Yes with double doors
13.Specified pathogens stored in laboratory	Yes	Yes	Yes
14.Double ended dunk tank required	-	Preferable	Yes
15.Protective clothing not worn outside laboratory	Yes	Yes	Yes
16.Showering required before exiting laboratory	-	-	Yes
17.Safety Officer responsible for containment	Yes	Yes	Yes
18.Staff receive special training in the requirements needed	Yes	Yes	Yes
C)Laboratory discipline	-	-	-
19.Warning notices for containment area	Yes	Yes	Yes
20.Laboratory must be lockable	Yes	Yes	Yes
21.Authorised entry of personnel	Yes	Yes	Yes
22.On entering all clothing removed and clean clothes put on	-	Yes	Yes
23.On exiting all laboratory clothes removed, individual must wash and transfer to clean side	-	Yes	-
24.Individual must shower prior to transfer to clean side	-	-	Yes
25.All accidents reported	Yes	Yes	Yes
D)Handling of specimens	-	-	-
26.Packaging requirements to be advised prior to submission	Yes	Yes	Yes
27.Incoming packages opened by trained staff	Yes	Yes	Yes
28.Movement of pathogens from an approved laboratory to another requires a licence	Yes	Yes	Yes
29.Standard Operating Procedures covering all areas must be available	Yes	Yes	Yes